JUN - 2 2009 Revision 03-11-2009

K090776

510(k) Summary

Submitter:			Date of Preparation: March 11, 2009
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: 60061
Contact name: Mr. Ron Haselhorst			
Contact title: Quality Assurance / Regulatory Affairs Manager			

Product Information: (Base)	
Trade name: MegaPulse Laser System	Model number: 2285011
Common name: Laser Instrument, Surgical, Powered	Classification name: Laser surgical instrument for use in general and plastic surgery and in dermatology, Class II. (21 CFR 878.4810, Product Code GEX)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K001243	1 Dornier Medilas H Laser	1 Dornier
2 K002308	2 Trimedyne OmniPulse Models 1210, 1210-VHP, and 1500-A	2 Trimedyne, Inc.
3 K051399	3 AURIGA	3 WaveLight Laser Tech., AG.

Product Information: (Laser Fibers)	
Trade name: MegaPulse Laser Fibers	Model number: 48750.xxx
Common name: Laser Fibers, Single Use	Classification name: Laser fibers have not been specifically classified by FDA. Laser fibers are an accessory to Laser-Powered Instruments. Class II. (21 CFR 878.4810, Product Code GEX)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
K022544	1. Dornier Medilas H Laser Fiber Cables	1. Dornier MedTech America, Inc.
K943445	2. Megabeam Fiber Optic Delivery System	2. Ceramoptec, Inc. (Biolitec, Inc.)
K973172	3. Resposable Holmium Bare Fibers	3. Trimedyne, Inc.

Device Description:

The Richard Wolf Medical Instruments Corporation MegaPulse Laser System is comprised of a Holmium YAG laser base unit with integrated cooling unit and system specific laser fibers.

The laser system base contains the switching elements and interfaces, the display unit, the fiber connection point, components inside the laser system, and software. For a safe operation, essential functions and components are monitored automatically. The MegaPulse Laser system is designed with automated fiber recognition to ensure only permissible parameters are used. A warning message appears on the touch screen monitor and is accompanied by a signal should a fault or error occur.

The MegaPulse Laser Fibers are intended to be used in with MegaPulse Laser System to deliver laser energy. The laser fiber delivery system is typically used in conjunction with a rigid or flexible endoscope to provide access to the surgical procedure site. The laser fiber works on the principle of internal reflection. Laser energy is focused into the fiber at the proximal end and it travels the length of the fiber by means of total reflection. The fiber contains the laser beam and channels the laser energy from the proximal end of the fiber to its distal end. The laser fibers are single-use sterile packaged. They are similar if not equivalent in design and performance to other legally marketed laser fibers with an integrated fiber identification system designed to work only with the MegaPulse laser system base.

Intended Use:

The Richard Wolf Medical Instruments Corporation MegaPulse Laser System is intended to be used in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic, and colonscopic) procedures, breaking up stone, cutting (i.e. structures), ablation, vaporization, excision, incision, and coagulation of tissue in the specialties as Urology, Pulmonology, Arthroscopy, Gastroenterology, Gynecology, ENT, Lithotripsy, Orthopedics, Discectomy, and General Surgery.

Indications and Field of Use:

The MegaPulse 2285 is a **Class 4** laser emitting laser radiation at a wavelength of approx. 2080 nm. This particular wavelength is transmitted by a fiberoptic wave guide (glassfiber) allowing efficient treatment in conjunction with the application – related preselected parameters with at the same time minimum stress for the adjacent tissue.

This device must only be used by adequately qualified and trained medical personnel.

These indications and field of use are equivalent if not identical to the named predicate devices.

Technological Characteristics:

The Richard Wolf MegaPulse Laser System and its predicate devices may have minor differences in the technological characteristics; however, those differences do not raise new questions of safety or efficacy. Thus the Richard Wolf Medical Instruments Corporation MegaPulse Laser System is substantially equivalent to the predicate devices in terms of technological characteristics.

Performance Data:

Bench testing of specifications were verified and validated and software validation was performed to assure safe and effective operation / control of software functions. The Richard Wolf MegaPulse Laser System meets the same safety standards as the named predicate devices.

Clinical Data:
No clinical data was required to confirm safety and effectiveness.

Rational for Substantial Equivalence:
The Richard Wolf Medical Instruments Corporation MegaPulse Laser System laser fibers perform the same function, have basically the same material composition and are substantially equivalent to the lasers fiber delivery systems cleared for Dornier MedTech. America, Inc. (K022544), Biolitec Inc. (K943445), and Trimedyne (K973172).

The Richard Wolf Medical Instruments Corporation MegaPulse Laser base shares the same general indications for use and has similar functional features and technological characteristics as the named predicate devices. These minor differences do not raise new questions of safety or efficacy. For these reasons The Richard Wolf Medical Instruments Corporation MegaPulse Laser System is substantially equivalent to the existing 510(k) cleared devices sold by: Dornier (K001243), Wavelight Laser Technologies (K051399), and Trimedyne (K002308).

Thus the Richard Wolf Medical Instruments Corporation MegaPulse Laser System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2009

Richard Wolf Medical Instruments Corporation
% Mr. Ron Haselhorst
Quality Assurance/Regulatory Affairs Manager
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K090776
Trade/Device Name: MegaPulse Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 11, 2009
Received: March 23, 2009

Dear Mr. Haselhorst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K 090776.

Device Name: MegaPulse Laser System

Intended Use:
The Richard Wolf Medical Instruments Corporation MegaPulse Laser System is intended to be used in surgical procedures involving open and endoscopic (laparoscopic, hysteroscopic, bronchoscopic, gastroenteroscopic, and colonscopic) procedures, breaking up stones, cutting (i.e. structures), ablation, vaporization, excision, incision, and coagulation of tissue in the specialties as: Urology, Pulmonology, Arthroscopy, Gastroenterology, Gynecology, ENT, Lithotripsy, Orthopedics, Discectomy, and General Surgery.

Prescription use ✓ and / or Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ANOTHER PAGE IF NEEDED

Concurrence of CDHR office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090776